

REMARKS

Applicant respectfully requests reconsideration. Claims 1, 2, 5-9, 11, 16, 17, 19-22 and 24-29 were pending in this application. By this Amendment, Applicant is canceling claims 9 and 28 without prejudice or disclaimer. Claims 2, 5-8, 11, 16, 19, 20, 24-27 and 29 have been amended. Support for the claim amendments can be found in the instant specification on at least page 9, line 12, and in the claims as originally filed. Therefore, claims 1, 2, 5-8, 11, 16, 17, 19-22, 24-27 and 29 are pending, with claims 1 and 19 being independent claims.

No new matter has been added.

For the record, Applicant does not concede the correctness of the Examiner's comments in regard to the art made of record and not relied upon.

Rejections under 35 U.S.C. §112

The Examiner has rejected claim 19 under 35 U.S.C. §112, first paragraph, as allegedly containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. According to the Examiner, the phrase "a sequence upstream from the transcriptional start site of a mammalian milk protein which includes a milk protein promoter" is new matter. It is unclear whether the Examiner also objected to this phrase in claim 19, but the response to the written description rejection fully responds to such a new matter rejection.

Applicant respectfully traverses. The phrase that the Examiner alleges is not provided in the description of the instant specification is in fact disclosed in the original specification on page 5, lines 18-22, and provides that "A sequence upstream from the transcription start site in the genomic clone constitutes a putative 'promoter', a genomic sequence preceding the gene of interest and presumed to be involved in its regulation." The beginning of the paragraph which provides this description discloses that promoters can be isolated from milk protein genes, making clear that the "putative promoter" can be a milk protein promoter. Accordingly, the rejected phrase does not constitute new matter, as it is clearly disclosed in the instant specification.

Accordingly, withdrawal of the rejection under 35 U.S.C. §112, first paragraph, is respectfully requested.

The Examiner has also rejected claims 1, 2, 5-9, 11, 16, 17, 19-22 and 24-29 under 35 U.S.C. §112, second paragraph, for allegedly being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention.

Applicant respectfully traverses. One of ordinary skill in the art would clearly understand the use of the term "naturally" in the rejected claims based on the plain meaning of the term and context of the claims. A term is not required to be "an art accepted term" as argued by the Examiner. All that is required is that the meaning of the term in the context of the claim be clear to one of ordinary skill in the art. Applicant asserts that the context in which the term is used would be understandable to one of ordinary skill. The plain meaning of the phrase "promoter sequence which does not naturally control transcription of said gene" would be readily understood by one of ordinary skill in the art as one that is not involved in the transcription of the gene as found in nature (i.e., naturally).

Further, the use of the term is exemplified in the instant specification. For example, the promoter can be one "naturally associated with any protein which is normally secreted into mammalian milk" (see, e.g., pages 3, line 24, to page 4, line 2). Similarly, if the protein is normally secreted, the signal sequence can be "that which is naturally associated with the desired protein" (See, e.g., page 6, lines 22-23). Alternatively, especially if the desired protein is not normally secreted, the secretion signal can be one associated with another secreted protein or a milk protein (See, e.g., page 7, lines 5-8).

Further, Applicant maintains that "derived from SV40 virus DNA" is also sufficiently definite. However, in the interest of expediting prosecution, claims 8 and 27 have been amended and claims 9 and 28 have been canceled. Accordingly, Applicant believes that the rejection in regard to this phrase is now moot.

Finally, Applicant maintains that the recitation of "a sequence upstream from the transcriptional start site of a mammalian milk promoter which includes a milk protein promoter" is sufficiently definite. However, in the interest of expediting prosecution, claim 19 has been amended. Accordingly, the rejection in regard to this phrase is believed to be moot.

Accordingly, withdrawal of the rejections of under 35 U.S.C. §112, second paragraph, is respectfully requested.

Double Patenting Rejections

The Examiner has rejected claims 1, 2, 5-9, 11, 16, 17, 19-22 and 24-29 on the ground of nonstatutory obviousness-type double patenting, as allegedly these claims are unpatentable over claims 1-5 of U.S. Patent No. 6,727,405 and claims 1-41 of U.S. Patent No. 7,045,676.

Applicant notes that the claims are rejected on other grounds. When the claims are in an otherwise allowable form, Applicant will file a terminal disclaimer at that time, if necessary.

Rejections Under 35 U.S.C. §102

The Examiner has rejected claims 1, 2, 5-9, 16, 17, 19-22 and 24-28 under 35 U.S.C. §102 as allegedly being anticipated by Qasba et al. (1984, Nature 308: 377-380).

Applicant respectfully traverses. Qasba et al. do not teach all of the elements of the rejected claims. For example, Qasba et al. do not teach the elements of a mammalian milk promoter which does not naturally control transcription of said gene or of a sequence that controls the transcription and is upstream from the transcriptional start site of a mammalian milk protein and which does not naturally control the transcription of said gene. Qasba et al. teach a nucleotide sequence of the rat alpha-lactalbumin gene, including its promoter sequence. According to the Examiner, a fragment of the promoter sequence is allegedly described by Qasba et al. and allegedly would result in an expression profile different from the "natural" expression profile. This explanation is not sufficient to sustain the rejection. Applicant cannot deduce from Qasba's teachings that this alleged fragment is a mammalian milk promoter which does not naturally control transcription of said gene or is a sequence that controls the transcription and is upstream from the transcriptional start site of a mammalian milk protein and which does not naturally control the transcription of said gene. In addition, Applicant cannot deduce from Qasba's teachings that a construct that falls within the scope of the rejected claims is even provided.

Accordingly, withdrawal of this rejection is respectfully requested.

The Examiner has also rejected claims 19-22 and 24-28 under 35 U.S.C. §102 as being allegedly anticipated by Cilibero et al. (1985, Cell 41: 531-540).

Applicant respectfully traverses. Applicant maintains that the Examiner's interpretation of the claim language is not correct. The upstream sequence is one that is not only upstream from the transcriptional start site of a mammalian milk protein sequence but is one that also controls transcription. In addition, Applicant maintains that the teachings of Cilibero et al. do not provide the constructs of the rejected claims, namely one that encodes a gene, a transcription controlling sequence upstream from the transcriptional start site of a mammalian milk protein and which does not naturally control transcription of said gene and a peptide enabling secretion of said protein.

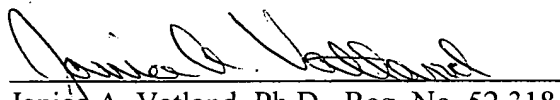
Accordingly, withdrawal of this rejection is respectfully requested.

CONCLUSION

A Notice of Allowance is respectfully requested. The Examiner is requested to call the undersigned at the telephone number listed below if this communication does not place the case in condition for allowance.

If this response is not considered timely filed and if a request for an extension of time is otherwise absent, Applicant hereby requests any necessary extension of time. If there is a fee occasioned by this response, including an extension fee, that is not covered by an enclosed check, please charge any deficiency to Deposit Account No. 23/2825.

Respectfully submitted,



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